



**DEVELOPMENT OF DIABETES MELLITUS MEDICATION COMPLIANCE INSTRUMENT**

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**ABSTRACT**

Medication adherence is an important factor in the management of type 2 DM. Non-adherence in taking medication can worsen the patient's health condition, increase glycated hemoglobin (HbA1c) levels, and increase the risk of complications such as neuropathy, nephropathy, and cardiovascular disease. Research shows that only about 50-60% of patients comply with prescribed medication. The aim of this research is to develop a research instrument on medication adherence in Diabetes Mellitus patients. The type of research used is Research and Development. To produce a research instrument product on compliance with taking diabetes mellitus medication and to test its effectiveness, the research process is carried out through two main stages, namely the content validity stage and the validity and reliability test stage. Content validity is evaluated by 10 expert panels. While the validity and reliability tests were carried out on 30 respondents, namely Type 2 Diabetes Mellitus patients aged 19-40 years who are outpatients in Mardhatillah Hospital Pemalang, Central Java. Validity test analysis using Pearson Product Moment correlation (r) by looking at the output results of Corrected Item Total Correlation, while the Reliability Test is measured by the Cronbach Alpha statistical test. The results of this study indicate that all items in the diabetes mellitus medication adherence instrument meet the content validity criteria based on the assessment for expert ( $I-CVI \geq 0.75$ ). Furthermore, based on the validity test of 15 question items, it is known that for statements 1 to 15, the lowest calculated r is 0.436 and the highest calculated r is 0.779, so that the 15 statements of the DM medication adherence questionnaire are valid. Meanwhile, the results of the reliability test on the 15 items of this research questionnaire have a total Cronbach's Alpha value per variable  $> 0.60$ , so that the research questionnaire is reliable (consistent). The research instrument in the form of a questionnaire on adherence to taking DM medication consisting of 15 questions was declared to meet the criteria of content validity, validity and reliability, so it can be used as a research instrument. With valid and reliable instruments, health workers can monitor patient compliance more effectively, support the success of therapy and improve the quality of life of patients with diabetes mellitus.

Keywords: content; diabetes mellitus; instrument development; medication adherence; reliability; validity

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**INTRODUCTION**

Diabetes Mellitus (DM) is one of the non-communicable diseases that is a global health problem with increasing prevalence. Based on data from the International Diabetes Federation (IDF), in 2020 there were around 537 million adults living with diabetes, and this figure is expected to increase to 643 million by 2030 in Indonesia, type 2 DM is a serious challenge with high prevalence and significant mortality rates (Ningrum, 2020). Medication adherence is a crucial factor in the management of type 2 DM. Non-adherence in taking medication can worsen the patient's health condition, increase glycated hemoglobin levels (HbA1c), and increase the risk of complications such as neuropathy, nephropathy, and cardiovascular disease. Research shows that only about 50-60% of patients comply with prescribed medication. (Zairina et al, 2022) Various factors can affect the level of patient compliance, including age, gender, education level, level of knowledge, number of drugs consumed, family support, and support from health workers

(Ningrum, 2020). Studies also show that social support, especially from family, plays an important role in increasing patient compliance with treatment (Almira et al., 2019).

In an effort to improve patient compliance, the development of valid and reliable research instruments is essential to measure the level of drug compliance objectively. The right instrument can help health workers evaluate the effectiveness of treatment interventions and design more effective education programs. Previous studies have highlighted the importance of developing a Medication Monitoring (PMO) model as an intervention strategy to improve patient compliance. With a comprehensive instrument, it is expected to obtain accurate data on factors that influence patient compliance, so that more targeted interventions can be implemented. Therefore, the development of research instruments on medication compliance in DM patients is urgently needed. With valid and reliable instruments, health workers can monitor patient compliance more effectively, support successful therapy, and reduce the risk of more serious complications. The purpose of this study was to develop a research instrument on medication compliance in Diabetes Mellitus patients.

## METHOD

The type of research used is Research and Development . To produce a research instrument product on compliance with taking diabetes mellitus medication and test its effectiveness, this research process is carried out through two main stages: (1) the content validity stage and (2) the Validity and Reliability Test stage. (Sugiono, 2019); (Haikal, 2019)Content validity refers to to what extent the items in the instrument able to represent the theoretical construct being measured, and is an important form of evidence in support validity instrument study (Yusoff, 2019), (Suryadi et al, 2023). Meanwhile, the validity and reliability test of the instrument was analyzed using statistical tests. The sample for developing the validity and reliability test instrument in this study was conducted on 30 respondents, namely Type 2 Diabetes Mellitus patients aged 19-40 years who were outpatients. in Mardhatillah Hospital Pemalang, Central Java. Validity test analysis using Pearson Product Moment correlation (r) by looking at the output results of Corrected Item Total Correlation , while the Reliability Test is measured by the Cronbach Alpha statistical test. .( Sugiono, 2019)

## RESULT

### Content Validity

Stages Content validity in this study includes several steps which are described as follows:

First step: Preparation of content validity form.

Researcher compile form validity content use give clarity about task which must be carried out by experts (expert panel). This form aims to facilitate systematic and consistent assessment of the suitability of each item to the intended construct. Following form content validity: Para expert requested for evaluate Contents from each scale. Scale evaluation Which will used by for expert is scale evaluation ordinal Likert. The scale is: 1. not relevant, 2 = somewhat relevant, 3 = quite relevant, and 4 = very relevant (Larsson, 2015), (Suryadi et al, 2023). Table 1 below is the content validation form:

Table 1.

Content Validation Form Diabetes Mellitus Medication Compliance Instrument

No	Statement	Rating Scale			
		1	2	3	4
Compliance with Medication Times					
1	I always take my diabetes medication according to the schedule recommended by my doctor.				
2	I never miss a dose of medicine even when I'm busy.				

No	Statement	Rating Scale			
		1	2	3	4
3	I follow the doctor's instructions in arranging the time of taking the medicine before or after eating.				
<b>Compliance with Drug Dosage</b>					
4	I always take the medication at the prescribed dose without reducing or increasing the dose myself.				
5	I understand the importance of adhering to the dosage prescribed by your doctor.				
6	If I forget to take my medication, I immediately consult a medical professional for appropriate action.				
<b>Compliance in Treatment Supervision</b>					
7	I routinely check my HbA1c levels according to the schedule determined by my doctor.				
8	I follow the advice of the Drug Supervisor (PMO) or health workers regarding drug consumption.				
9	I feel helped by the support from my family or PMO in reminding me when to take my medication.				
<b>Awareness and Understanding of Treatment</b>					
10	I understand the benefits of the diabetes medication I take to keep my blood sugar levels stable.				
11	I am aware of the risks of complications that may arise if I do not comply with the treatment.				
12	I got enough information about the side effects of the drug from health workers.				
<b>Factors Affecting Compliance</b>					
13	I feel the cost of diabetes treatment is still affordable.				
14	I did not experience any significant side effects so I remained compliant with the treatment.				
15	I have easy access to regular diabetes medication.				

Note:

- 1 = Not Relevant
- 2 = Somewhat Relevant
- 3 = Quite Relevant
- 4 = Very Relevant

### Step second: Election panel expert (*expert panels*)

At this stage, the researcher appointed ten people as a panel of experts to conduct an assessment of the Diabetes Mellitus medication adherence instrument . The composition of the panel reflects the diversity of scientific backgrounds and professional experiences relevant to the research topic, namely: three internal medicine specialists (A1-A3), three general practitioners implementing the DM program (A4-A6), three person Health workers are health promotion experts at the Community Health Center (A7-A9), One person in charge of the program at the District Health Office (A10). The selection of a panel of experts with varying backgrounds aims to obtain a comprehensive perspective in evaluating readability, relevance, as well as conformity Contents Items with context And condition current population target. Assessment done in a way online via platform Google Form, which allow the review process is carried out flexibly and efficiently. (Suryadi et al, 2023)

### Step third: Review domain And Items and giving score by panel of experts.

On stage This, ten person from panel expert requested For do evaluation critical to each domain and item in the instrument before providing a quantitative assessment. Experts were asked to consider the appropriateness of the item to the domain in question, and to provide feedback both verbally and in writing to improve the clarity, relevance, and accuracy of the item content. All comments provided were analyzed and considered in the revision process to improve the structure and content of the instrument. Assessment of each item was carried out independently by each expert, using a scale four points: 1 = not relevant, 2 = not very

relevant, 3 = quite relevant, and 4 = very relevant (Police, 2006). Scale This used For count index validity content that will reflect the level of agreement of experts regarding the relevance of items in measuring the intended construct. (Suryadi et al, 2023)

**Step fourth: Calculation Content Validity Index (CVI).**

In this study, content validity was analyzed by calculating *the Item-Level Content Validity Index (I-CVI)* and *Scale-Level Content Validity Index (S-CVI)*. Before the calculation is carried out, the score evaluation from experts recoded to in dichotomous format: score 3 and 4 are categorized as “relevant” and given a value of 1, while scores 1 and 2 are categorized as “not relevant” and given a value of 0. The I-CVI is calculated by dividing the number of experts who provided score 3 or 4 to a Items with amount total expert. Mark minimum I-CVI which can accepted is 0 .75 . Temporary That, S-CVI counted as average from all I- CVI Items in instrument. Mark limit minimum Which accepted For S-CVI is 0 .75 . Items that have an I-CVI value or S-CVI below the threshold limit which has been specified considered not to meet the content validity criteria and therefore will be eliminated from the instrument (Putri et al, 2025), (Suryadi et al, 2023). The following Table 2 is the calculation of the content validity index:

Table 2.  
Mark I-CVI and S-CVI Items instrument Based on Evaluation Panel of Experts

No.	Statement	A1	A2	A3	A	A5	A6	A7	A8	A9	A10	Number of Numbers that approved	CVI Items
1	I always take my diabetes medication according to the schedule recommended by my doctor.	1	1	1	1	1	1	1	1	1	1	10	1.00
2	I never miss a dose of medicine even when I'm busy.	1	0	1	1	1	1	1	1	1	1	9	0.90
3	I follow the doctor's instructions in arranging the time of taking the medicine before or after eating.	1	1	1	1	1	1	1	1	1	1	10	1.00
4	I always take the medication at the prescribed dose without reducing or increasing the dose myself.	1	1	1	1	1	1	1	1	1	1	10	1.00
5	I understand the importance of adhering to the dosage prescribed by my doctor.	1	1	1	1	1	1	1	1	1	1	10	1.00
6	If I forget to take my medication, I immediately consult a medical professional for appropriate action.	1	1	1	1	1	1	1	1	1	1	10	1.00
7	I routinely check my HbA1c levels according to the schedule determined by my doctor.	1	1	1	1	1	1	1	1	1	1	10	1.00
8	I follow the advice of the Drug Supervisor (PMO) or health workers regarding drug consumption.	1	1	1	1	1	1	1	1	1	1	10	1.00

9	I feel helped by the support from my family or PMO in reminding me when to take my medication.	1	1	0	1	1	1	1	1	1	1	9	0.90
10	I understand the benefits of the diabetes medication I take to keep my blood sugar levels stable.	1	1	1	0	1	1	0	1	1	1	8	0.80
11	I am aware of the risks of complications that may arise if I do not comply with the treatment.	0	1	1	1	1	1	1	1	1	1	9	0.90
12	I got enough information about the side effects of the drug from health workers.	1	1	1	1	1	1	1	1	1	1	10	1.00
13	I feel the cost of diabetes treatment is still affordable.	1	0	1	1	1	1	1	1	1	1	9	0.90
14	I did not experience any significant side effects so I remained compliant with the treatment.	1	1	1	1	1	1	1	1	1	1	10	1.00
15	I have easy access to regular diabetes medication.	1	1	1	1	1	1	1	1	1	1	10	1.00
												I-CVI	15/15 = 1.00
												S-CVI/UA	0.960

The results of this study indicate that all items in the diabetes mellitus medication adherence instrument meet the content validity criteria based on the assessment. for expert. Mark *Item Level Content Validity Index* (I-CVI) For every Items ranged from 0.80 to 1.00, while the overall *Scale-Level Content Validity Index* (S-CVI/UA) value was 0.96. This value indicates that the items contained in the diabetes mellitus medication adherence instrument has considered relevant by majority panel expert Which consists of from various background scientific background And experience. Achievement mark  $I-CVI \geq 0.75$  on all over The items indicate that each item is considered capable of representing the construct of adherence to taking diabetes mellitus medication. Based on the assessment, it is known that most items obtained the maximum value (1.00), which indicates full agreement from the entire panel of experts regarding the relevance of the contents of the instrument items. (Putri et al, 2025), (Suryadi et al, 2023)

### Test of Instrument Validity and Reliability

Based on the content validation stages, the following are the results of the validity test compliance instrument which will undergo the validity and reliability test stages:

Table 3.

Diabetes Mellitus Medication Compliance Instrument		Answer				
		1	2	3	4	5
Compliance with Medication Times						
1	I always take my diabetes medication according to the schedule recommended by my doctor.					
2	I never miss a dose of medicine even when I'm busy.					
3	I follow the doctor's instructions in arranging the time of taking the medicine before or after eating.					
Compliance with Drug Dosage						
4	I always take the medication at the prescribed dose without reducing or increasing the dose myself.					
5	I understand the importance of adhering to the dosage prescribed by your					

	doctor.
6	If I forget to take my medication, I immediately consult a medical professional for appropriate action.
Compliance in Treatment Supervision	
7	I routinely check my HbA1c levels according to the schedule determined by my doctor.
8	I follow the advice of the Drug Supervisor (PMO) or health workers regarding drug consumption.
9	I feel helped by the support from my family or PMO in reminding me when to take my medication.
Awareness and Understanding of Treatment	
10	I understand the benefits of the diabetes medication I take to keep my blood sugar levels stable.
11	I am aware of the risks of complications that may arise if I do not comply with the treatment.
12	I got enough information about the side effects of the drug from health workers.
Factors Affecting Compliance	
13	I feel the cost of diabetes treatment is still affordable.
14	I did not experience any significant side effects so I remained compliant with the treatment.
15	I have easy access to regular diabetes medication.

Note:

1 = Strongly Disagree

2 = Disagree

3 = Neutral

4 = Agree

5 = Strongly Agree

### Validity Test

Table 4.  
Validity Test Results

No	Questionnaire Items	Corrected Item Value- Total Correlation ( <i>Pearson Product Moment Test</i> )	Note
1	Questionnaire 1	0.696	Valid
2	Questionnaire 2	0.436	Valid
3	Questionnaire 3	0.469	Valid
4	Questionnaire 4	0.523	Valid
5	Questionnaire 5	0.479	Valid
6	Questionnaire 6	0.531	Valid
7	Questionnaire 7	0.628	Valid
8	Questionnaire 8	0.526	Valid
9	Questionnaire 9	0.448	Valid
10	Questionnaire 10	0.540	Valid
11	Questionnaire 11	0.779	Valid
12	Questionnaire 12	0.524	Valid
13	Questionnaire 13	0.482	Valid
14	Questionnaire 14	0.772	Valid
15	Questionnaire 15	0.605	Valid

Research using the questionnaire method requires a validity test. Validity testing is useful for determining the validity or suitability of the questionnaire used by researchers to obtain data from respondents or research samples (Ghozali, 2011). Validity testing with *Pearson Product Moment Correlation* uses the principle of connecting each item or question score with the total score obtained from respondents' answers to the questionnaire. The basis for decision making in the validity test is done by *comparing* the calculated r value with the table r value with the following criteria:

a) if the calculated r value > r table , then the questionnaire item is declared valid;

b) if the  $r_{\text{calculated}} < r_{\text{table}}$ , then the questionnaire item is declared invalid.

The validity and reliability test of the questionnaire was conducted on 30 people. This was done in order to obtain a distribution of measurement results close to normal. (Notoatmojo, 2018). The validity test of the research questionnaire was conducted on 30 respondents, namely Type 2 Diabetes Mellitus patients aged 19-40 years who were outpatients. in Mardhatillah Hospital Pematang. Based on table 4, it is known that the results of the validity test of 15 question items based on calculations with *the SPSS for Windows program* (N = 30;  $\alpha = 5\%$ ;  $df = n-2$ ;  $r_{\text{table}} = 0.361$ ) are known that for statements 1 to 15, the lowest  $r_{\text{calculated}}$  is 0.436 and the highest  $r_{\text{calculated}}$  is 0.779. Thus, the 15 statements of the DM medication adherence questionnaire are valid.

### Reliability Test

Reliability testing can be done simultaneously for all the questions or items in the research questionnaire. (Ghozali, 2011). The basis for decision making in reliability testing is as follows:

- a) if *the Cronbach's Alpha* value  $> 0.6$  then the questionnaire is declared reliable or consistent;
- b) if *the Cronbach's Alpha* value  $< 0.6$  then the questionnaire is declared unreliable or inconsistent.

The results of calculations using *the SPSS for Windows program* (N= 30;  $\alpha= 5\%$ ) the following reliability test results were obtained:

Table 5.  
Reliability Test Results

No	Questionnaire Items	<i>Cronbach's Alpha</i> Value	Note
1	Questionnaire 1	0.789	Reliable
2	Questionnaire 2	0.796	Reliable
3	Questionnaire 3	0.798	Reliable
4	Questionnaire 4	0.795	Reliable
5	Questionnaire 5	0.770	Reliable
6	Questionnaire 6	0.771	Reliable
7	Questionnaire 7	0.765	Reliable
8	Questionnaire 8	0.798	Reliable
9	Questionnaire 9	0.797	Reliable
10	Questionnaire 10	0.763	Reliable
11	Questionnaire 11	0.743	Reliable
12	Questionnaire 12	0.764	Reliable
13	Questionnaire 13	0.769	Reliable
14	Questionnaire 14	0.748	Reliable
15	Questionnaire 15	0.759	Reliable

Table 5 shows that each questionnaire in the 15-item research questionnaire has a total *Cronbach's Alpha* value per variable  $\geq 0.60$ , so that the research questionnaire is reliable (consistent) and can be used in research.

### DISCUSSION

Diabetes mellitus is a disease that requires long-term therapy and can cause complications in various organs. Knowledge is an important factor in the formation of good health behavior including medication adherence. (Hamid et al, 2022). The dimensions of the diabetes mellitus medication adherence instrument include: medication adherence, medication dosage adherence, medication monitoring adherence, awareness and understanding of treatment and factors that influence adherence. The importance of instruments for medication adherence in DM patients is also supported by previous studies which state that medication adherence is one of the factors that contribute to quality of life. (Meidikayanti, et al. 2017)

Medication adherence instruments play a crucial role in the management of Diabetes Mellitus (DM), especially type 2, which requires long-term treatment regularity. Without accurate measuring instruments, health workers will have difficulty identifying patients at risk of low adherence, which can lead to increased complications and health care costs. A recent study by showed that only 39.4% of type 2 DM patients had high levels of adherence and this adherence was significantly correlated with more controlled HbA1c levels. (Soraya et al, 2023). The use of this instrument is very important in planning interventions and health policies. With accurate adherence data, educational and pharmacological interventions can be tailored specifically to patient needs. One study found that adherence to treatment was closely correlated with quality of life and glycemic control in patients with type 2 DM. (Eliza et al, 2023)

## CONCLUSION

The results of this study indicate that all items in the diabetes mellitus medication adherence instrument meet the content validity criteria based on the assessment. for expert ( $I-CVI \geq 0.75$ ). Furthermore, the results of the validity test of 15 question items show that for statements 1 to 15, the lowest calculated  $r$  is 0.436 and the highest calculated  $r$  is 0.779, so that the 15 statements of the DM medication adherence questionnaire are valid. Meanwhile, the results of the reliability test on the 15 items of this research questionnaire have a total Cronbach's Alpha value per variable  $> 0.60$ , so that the research questionnaire is reliable (consistent), thus the questionnaire instrument on DM medication adherence can be used for research.

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